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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,148	04/26/2001	Chester Struble	P-9440	6240

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EXAMINER	
SCHAETZLE, KENNEDY	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/842,148	STRUBLE, CHESTER	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 28, 2005 has been entered.

Claim Rejections - 35 USC § 102/103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-8 and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen (Pat. No. 5,156,148).

Regarding claim 1, Cohen disclose a system for treating cardiac arrhythmia comprising a sensing lead (note col. 8, lines 38-46), a processor configured to receive electrical signals indicative of heart rate and to detect and discriminate between atrial and ventricular arrhythmias and generate an arrhythmia signal (note the paragraph abridging cols. 4 and 5, col. 6, lines 28-37, and col. 10, lines 43-55), a drug delivery system 18 configured to receive the arrhythmia signal comprising a first drug pump (e.g., element 18a) containing a first drug (note col. 7, lines 29-37 and the various drugs

mentioned throughout Figs. 5A-5I), a second drug pump (e.g., element 18b) containing a second drug (again note the various drugs mentioned in the above recited figures), and first and second infusion apparatus coupled to the first and second drug pumps (the venous and/or arterial injection devices discussed in Fig. 2). The drug delivery system is configured to activate the first drug pump to dispense the first drug via the first infusion apparatus when the arrhythmia signal is indicative of atrial arrhythmia (see for example boxes 547 and 550 of Fig. 5C), and is configured to activate the second drug pump to dispense the second drug via the second infusion apparatus when the arrhythmia is indicative of ventricular arrhythmia (see for example boxes 503 and 510 of Fig. 5B).

Regarding the use of first and second drugs wherein the second drug differs from the first drug, Cohen teaches that the system may employ drug(s) (note plural form) and that the various arrhythmias may be treated singly or in *combination* (col. 7, lines 18-37). Most assuredly if one was to implement the treatment defined by the flowcharts of Figs. 5A-5I which call for a variety of different drugs to be used depending upon the particular heart condition detected, one would necessarily have to provide at least first and second drug pumps containing respective first and second drugs.

Regarding the use of a sensing lead, although the examiner considers conventional EKG electrodes such as discussed by Cohen and referred to above, to pertain to leads (the examiner notes that a variety of artisans equate the term "electrodes" to the term "leads" even though such a comparison is not entirely accurate), those of ordinary skill in the art would have seen the provision of a lead or leads to obtain EKG signals for a device of the type shown in Fig. 7 to be blatantly obvious given their ubiquitous nature in implantable medical devices.

Regarding the recitations concerning the detection of cardiac arrhythmia *only* from heart rate and without regard to patient hemodynamic condition, the discrimination between an atrial arrhythmia and a ventricular arrhythmia as a function of *only* heart rate, and the generation of an arrhythmia signal as a function of the type of arrhythmia discriminated as a function of *only* the heart rate, the device of Cohen is still considered to meet these limitations because the fact that a device uses a combination of both

electrical signals and physiological signals to redundantly detect, discriminate and signal (the examiner considers any output result to be a signal) arrhythmias in order to enhance diagnostic accuracy, does not negate the fact that the device is capable of separately processing each information channel to form an independent analysis of the arrhythmia type. In other words, if the electrical signals indicative of heart rate are processed in a rate-only subsystem to discriminate between an atrial arrhythmia and a ventricular arrhythmia, and then later combined with an outcome brought on by independent analysis of the data produced by the physiological sensors, the system effectively has performed a detection, discrimination and signaling based only on the heart rate in combination with a detection, discrimination and signaling based only on the physiological signals. The examiner further wishes to direct the applicant's attention to the subject matter of canceled claim 19 wherein electrical signals indicative of heart rate (i.e., rhythm) are used to detect cardiac arrhythmias only from heart rate and without regard to patient hemodynamic condition.

Regarding claim 4, note the atrial and ventricular channels shown in Fig. 2 that carry the electrical heart signal to the processing device. Although Cohen does not explicitly state that the atrial (or ventricular) signal is obtained from a lead located in the atrium (or ventricle), the use of an atrial lead and a ventricular lead to respectively obtain an atrial signal and a ventricular signal would clearly have been considered blatantly obvious by anyone of ordinary competence in the art, especially given that this type of arrangement is old and conventional.

Regarding claim 5, the examiner considers the CPU 13 to comprise both a processor and a controller, with the control signal being input to the various drug delivery devices 18a-18d.

Concerning claim 7, the monitor/recorder is considered to represent an input/output device (note col. 7, lines 38-43).

In reference to claim 8, the examiner considers drug delivery devices 18a-18d to represent at least four drug pumps. Again, since more than three different types of drugs have been disclosed by Cohen as available for use with the invention depending

on the situation encountered, it would have been inherent that one of the drug pumps 18 would have contained a third drug.

Concerning claim 10, note box 510 of Fig. 5B.

5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen.

Regarding claim 9, Cohen does not explicitly refer to the use of a first drug selected from the group consisting of digitalis and beta blockers. Clearly the decision as to which particular medication should be used in the treatment of the patient would reside with the patient's physician, as the physician is in the best position to ascertain the condition of the patient. Those of ordinary skill in the art would have therefore considered the exact drug to be employed from the list of known anti-arrhythmia drugs to be an obvious physician's prerogative.

Response to Arguments

6. Applicant's arguments filed May 16, 2005 have been fully considered but they are not persuasive.

The applicant argues that the limitation concerning the use of a second drug different from a first drug distinguishes over the Cohen invention, since there is no suggestion in the prior art disclosure for incorporating different drugs. The examiner disagrees with this assessment of the Cohen reference as argued above in the rejection under paragraph 4. Cohen discloses both the use of multiple drug pumps, as well as the use of multiple drugs (see Fig. 2, elements 18a-18d and Figs. 5A-5I where different drugs are disclosed).

Conclusion

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued

examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
August 12, 2005

KENNEDY SCHAETZLE
PRIMARY EXAMINER